TAB E K955530

SUMMARY OF SAFETY AND EFFECTIVENESS UPON WHICH SUBSTANTIAL EQUIVALENCE IS BASED

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DEVICE NAME:

CLASSIFICATION NAME: Vascular Graft Prosthesis 6 mm and greater diameter
COMMON/USUAL NAME: Vascular Graft
TRADE/PROPRIETARY NAME: DIASTAT® VASCULAR ACCESS GRAFT

The DIASTAT Vascular Access Graft, intended for use as a vascular prosthesis in patients requiring vascular access, and which may be cannulated within one week of implantation, is substantially equivalent to various configurations of legally marketed predicate DIASTAT Vascular Access Grafts, various configurations of GORE-TEX® Vascular Grafts and the Atrium Plasma TFE™ Vascular Graft. DIASTAT Vascular Access Grafts are subject to the same general Quality Assurance systems and controls as GORE-TEX Vascular Grafts.

Substantially equivalent performance is demonstrated by a variety of mechanical and non-clinical *in vivo* tests. Reduced fluid leakage was demonstrated in bench testing using water, a liquid more likely to leak than heparinized blood. Animal testing confirmed this performance characteristic, with reduced times to hemostasis and reduced blood loss *in vivo*, and also demonstrated reduced incidence of hematoma.

Early cannulation techniques, including poor aseptic practice, and cannulation into swollen tissue, may tend to increase the risk of infection and thereby affect graft patency. These risks are addressed in the proposed labeling changes emphasizing strict aseptic technique for early cannulations.

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A prospective randomized clinical study of early cannulation of the DIASTAT Vascular Access Graft was not performed. The DIASTAT Vascular Access Graft possesses a specific mechanical low bleed feature which has been characterized in bench testing, tested *in vivo*, and observed in the clinical setting. These characterizations, tests, and observations confirm that the DIASTAT Vascular Access Graft is substantially equivalent to the Plasma TFE Vascular Graft for cannulation within one week of implantation, and that the DIASTAT Vascular Access Graft does not raise any new issues of safety and effectiveness.

The DIASTAT Vascular Access Graft is essentially an expanded PTFE vascular graft with the addition of one or more externally applied cannulation segments comprised of expanded PTFE fibers and an expanded PTFE covering. The graft is provided with or without external reinforcement in the form of FEP rings which may be fixed or removable, and in either extensible or non-stretch configurations. A comparison of the technological characteristics of the DIASTAT Vascular Access Graft and predicate devices reveals that no new types of safety and effectiveness questions are raised. No new biocompatibility or blood-contact issues are presented by the DIASTAT Vascular Access Graft.

The claims, labeling, and intended use of the DIASTAT Vascular Access Graft are substantially equivalent to those for the predicate DIASTAT Vascular Access Graft, all other GORE-TEX Vascular Grafts, and the Plasma TFE Vascular Graft. They have been modified only as necessary to accurately describe the product and to ensure that adequate and proper instructions for use as a vascular access prosthesis are provided.